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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,310	02/22/2007	Yoshiaki Uchida	0760-0354PUS1	5155

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EXAMINER
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LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

NOTIFICATION DATE	DELIVERY MODE
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03/02/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/577,310	UCHIDA ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2009.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/06&amp;7/28/06</u>                                       | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of group I, claims 1-2, 6-8, 11 in the scope of monoclonal antibody produced by the hybridoma rSN-122 (FERM BP-10144) in the reply filed on Jan 02, 2009 is acknowledged. The traversal is on the ground(s) that the reference cited by the examiner against the unity of the invention for the same technical feature was published later than the date of the foreign priority document Japanese Application No. 2004-034268 filed on Oct. 31, 2003.
2. Applicants' argument has been respectfully considered. Upon further searching and considering the pending claims, the lack of unity is still destroyed in view of the reference by Che et al originally published in a Chinese magazine in July, 2003 (J. First Mil. Med. University 2003 Jul; 23(7):640-642), which was published earlier than the priority date of the foreign priority document filed on Oct 31, 2003.
3. However, during examining the Application, pending claims 3, 4, 6, 7 and 8 are rejoined with the elected group I.
4. Claims 1-4, 6-8 and 11 in the scope of monoclonal antibody with accession No. FERM BP-10144 are considered.
5. Claims 5, 9 and 10 are withdrawn from consideration.

### *Priority*

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).
7. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).
8. Failure to provide a certified translation may result in no benefit being accorded for the non-English application.
9. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

*Information Disclosure Statement*

10. The information disclosure statement filed on April 28, 2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

11. In particular, the references that are not provided with English can only be considered based on the Abstract(s) if the Abstracts are cited in English.

12. The English translated versions need to be provided in order for the examiner to consider the references in full content disclosure.

*Claim Rejections - 35 USC § 112*

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15. In particularly, it appears from reading the specification that for a successful practicing the claimed invention in claims 4 and 7, the hybridoma FERM BP-10144 is an essential element. However, Applicant's deposit statement on specification page 27, does not indicate the extent of public availability.

16. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of

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the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

17. If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

(a) during the pendency of this application, access to the deposits will be afforded to one determined by the commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(C) the deposits will be maintained in the public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposits will be replaced if they should become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-37 CFR 1.809 for additional explanation of these requirements.

*Claim Rejections - 35 USC § 102*

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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19. For the following rejections, Applicants are reminded: Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

20. Claims 1-2, 6, 8, 11 are rejected under 35 U.S.C. 102(a) as anticipated by Berry et al. (J. Virol. Method July 2004, Vol. 120, pp. 87-96).

21. Berry et al. describe a monoclonal antibody F26G15 specifically against the nucleoprotein of SARS virus. The monoclonal antibody is produced and isolated by removing mouse spleens, preparing spleen and myeloma cells and then fusing hybridoma with myeloma cells (See page 89). Berry et al. also teach using said isolated monoclonal antibody to perform an ELISA assay in an ELISA plate to detect a presence of SARS virus in combination with a secondary anti-mouse IgG-HRP conjugated and commercial ABTS substrate as well as other reagents, such as BAS containing PBS blocking buffer (See page 89). Therefore, the cited reference anticipates the claims.

22. Claims 1-3, 6, 8, 11 are rejected under 35 U.S.C. 102(b) as anticipated by Che et al. (A) (J. First Mil. Med. University 2003 Jul;23(7):640-642) or by Che et al. (B) (J. Clin. Microbial, July 2004, Vol. 42, No. 6, pp. 2629-2635) under 35 U.S.C. 102(a) in light of the teaching by Marr et al. (Science, May 2003, Vol. 300, pp. 1399-1404).

23. Che et al. in (A) and (B) disclose several isolated monoclonal antibodies against nucleoprotein of SARS related coronavirus (SARS-CoV N protein), such as NE4A4, NE8A11, NE1A17, N1E8, N8E1, N10E4, N10A4, N14A3, N14E19, N14E1, N14E7, N14B6, N10E2, N1A7 [pages 1630-2631 and Figs. 1 in Che (B)] The isolated monoclonal antibodies are produced by the following steps: i). expressing the N protein of SARS coronavirus by bacterial host cell BL21 transformed with an expression vector; ii). immunizing BALB/c mice with said purified recombinant N protein, iii). Fusing the splenocytes from the immunized mice with NS-1 myeloma cells; iv). Selected the anti-N protein monoclonal antibody by hybridoma by ELISA, wherein the ELISA is processed in a polystyrene 96 well-plate coated with recombinant N protein and enzyme or FITC conjugated secondary antibody against the mouse antibodies [ Che (A): Abstract and (B) in pages 2269-2230). Che et al. (A) and (B) also describe many other reagents such as a dilution buffer, a washing buffer as well as AEC substrate. It is noted although the

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precise nuclei acid sequence and amino acid sequence of the N protein is not explicitly disclosed, the reference teaches that the recombinant N protein is provided by University of Hong Kong, wherein the nucleic acid sequence and protein sequence of the N protein disclosed by University of Hong Kong are the same as the one cited in claims 3-4 in light of the teaching by Marra et al. (Science 2003, Vol. 300, pp. 1399-1404). Che et al. in (A) and (B) also disclose an immunoassay, i.e. an ELISA using HRP labeled secondary antibody or FITC labeled secondary antibody to recognize the mouse anti-SARS N protein, and hereby making a diagnosis of the presence of SARS virus. Che et al. also describe using polystyrene plate as a device coated with SARS N protein and then adding the anti-SARS monoclonal antibody and labeled secondary anti-mouse antibody. Therefore, the disclosures by Che et al. (A) and (B) meet the limitations of claims 1-3, 6, 8 and 11.

#### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Bao Qun Li/

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24.